DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

JUL 27 2015

Pare Surgical, Inc.
Mr. Richard P. Fleenor
President
7332 S. Alton Way, Unit H
Englewood, Colorado 80112

Re: K003102
Trade/Device Name: PARE Endoscopic Suturing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated (Date on orig SE ltr): December 27, 2000
Received (Date on orig SE ltr): December 28, 2000

Dear Mr. Fleenor,

This letter corrects our substantially equivalent letter of February 27, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication For Use

510(k) Number : K003102

Device Name: PARÈ Endoscopic Suturing System

Indication For Use: The PARÈ Endoscopic Suturing System will allow the surgical physician to suture soft tissue when doing gastroenterological procedures using the operating channel of a flexible endoscope.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X___ OR Over -The Counter Use____ (Per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K003102

K003102

INNOVATIVE
MEDICAL
DEVICES

PARÉ SURGICAL, INC.
7332 S. Alton Way, Unit H
Englewood, CO 80112

Phone: 303.689.0187
Fax: 303.689.0579

PARÉ

FEB 2 7 2001

510(k) Summary

As required under Section 513(i)(3)(A) of the Safe Medical Device Act of 1990, an adequate summery of any information respecting the safety and effectiveness follows:

A. General Information:

Name and address of submitter:	PARÉ Surgical, Inc. 7332 S. Alton Way, Suite H Englewood, CO 80112
Contact:	Richard Fleenor President Phone: 303.689.0187 Fax: 303.689.0579
Date of summery:	December 27, 2000
Name of device:	PARÉ Endoscopic Suturing System
Common name:	Endoscopic Suturing Device
Classification:	78KOG- Endoscopic Suturing Device

B. Predicate Devices:

Company	Trade Name	510(k) Number
1. PARÉ Surgical, Inc.	Quik-Stitch™ Endoscopic Suturing System	K953123
2. BARD	Bard Endoscipic Suturing System	K994290

C. Description:

The PARÉ Endoscopic Suturing System consists of three concentric tubes and a wire that can fit down the operating channel of a flexible endoscope. Each of the concentric tubes controls a function that is required to do soft tissue suturing at the distal end of the endoscope. These functions include:

1. A needle, which is used to puncture through the soft tissue
2. A loop, which is used to capture the free end of the suture.
3. A holder for the suture that is formed into a pre-tied knot.
4. A knot pusher, which also performs the function of cutting the suture once the knot is positioned and formed.

The device will be loaded only with sutures that have received FDA approval for human use.

D. Intended Use:

The PARÉ Endoscopic Suturing System will allow the surgical physician to suture soft tissue when doing gastroenterological procedures using the operating channel of a flexible endoscope.

E. Technological Characteristics Summary:

The technological characteristics of the PARÉ Endoscopic Suturing System is the same or similar to the predicate devices in that the materials used to manufacture these products are the same type of medical grade stainless steels and plastics. The products all share common features such as material types provide a means for driving a needle through soft tissue and capturing the suture in the distal side. They all suture soft tissue by manually actuating the needle with a handle mechanism. They all are designed to allow reloading of suture to deliver multiple stitches under endoscopic visualization. Further, the PARÉ Endoscopic Suturing System and the predicated devices have the same of similar intended use, that is too place stitches and tie suture material to approximate soft tissue under endoscopic visualization.

F. Performance Data:

Bench test results using fresh swine esophagus, stomach and colon soft tissue showed that the materials chosen to be utilized in the PARÈ Endoscopic Suturing System meet the established specifications necessary for consistent performance of its intended use. The device was invitro tested six times using the operating channel of an Olympus Colonoscope type CF-1T140 and six times using an Olympus Gastroscope type GIF-PQ20. In all experiments the device was able suture the soft tissue including the dropping of the pre-tied knot.

510(k) Number : K003102

Device Name: PARÈ Endoscopic Suturing System

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